

K970455

**510(K) SUMMARY**  
**(as required by 807.92(c))**

MAY - 8 1997

**Submitter of 510(k):** Regulatory & Marketing Services, Inc. (RMS)  
40178 U.S. 19 North  
Tarpon Springs, FL 34689

Phone: 813-942-3908  
Fax: 813-942-3828

**Contact Person:** Ed Ransom

**Date of Summary:** February 3, 1997

**Trade Name:** Dukal Non Adherent Pad

**Classification Name:** Dressing

**Predicate Device:** Kendall Non Adherent Dressing

**Device Description/****Comparison:**

<b>Material</b>	<b>Dukal</b>	<b>Kendall</b>
Thickness	47 mil	same
Delnet Fracture	5lb/in	same
T-Peel	700 lb/in	same
Absorptive Capacity	38 oz/yd <sup>2</sup>	same
MD Tensile	6lb/in	same
Basis weight	5.0 oz/yd <sup>2</sup>	same
Intended Use	Absorbent non adherent dressing is used as a topical dressing to cover a wound or operative site while providing absorbency.	same

**Intended Use:** Absorbent non adherent dressing is used as a topical dressing to cover a wound or operative site while providing absorbency.